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April 25, 2012



**Via Federal Express**

United States Environmental Protection Agency - East  
Attn: TSCA Section 8(e)  
Room 6428  
1201 Constitution Avenue, NW  
Washington, DC 20004

**Subject:** Notice in Accordance with Section 8(e): Results of a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD) 422) in Wistar Rats with 6,15-dihydroanthrazine-5,9,14,18-tetrone (CAS No. 81-77-6)

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (OECD) 422) in Wistar Rats with 6,15-dihydroanthrazine-5,9,14,18-tetrone (CAS No. 81-77-6), conducted by BASF SE, Ludwigshafen, Germany. The test substance is a colorant.

The aim of this study was to obtain initial information on the possible effects of CAS 81-77-6 on the integrity and performance of the male and female reproductive systems including gonadal function, mating behavior, conception, gestation and parturition. Furthermore, information about the general toxicological profile including target organs and no-observed-adverse-effect-level (NOAEL) after repeated oral administration should be elucidated.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; No. 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (22 Mar 1996)
- EPA, Health Effects Test Guidelines; OPPTS 870.3650: Combined Repeated Dose Toxicity Study With the Reproduction/Developmental Toxicity Screening Test (Jul 2000)

The test substance was administered by gavage to groups of 10 male and 10 female Wistar rats. The concentration levels were 0, 100, 300 and 1000 mg/kg bw/d. All animals were observed daily for any clinical signs during the study period. After a 14-day pre-mating period, the male and female parental animals were mated overnight in a 1:1 ratio until evidence of copulation (vaginal smear). The day on which sperm was detected was referred to as gestation day (GD) 0 and the following day as GD 1. The parental females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined.

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**The following is a summary of the most relevant results:**

**1000 mg/kg bw/d (of test group 3)**

- Complete litter loss in one animal of test group 3 (1000 mg/kg bw/d). This animal delivered no pups, but showed 10 implantation sites.
- Postimplantation loss of 19.1% in test group 3 vs. 2.8% in the control group
- Significantly decreased (up to 87%) food consumption during entire gestation period in females of test group 3.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

If you have any questions, please contact the undersigned at (973) 245-6693.

Sincerely,

*Janet Cerra*

Janet Cerra  
Product Regulatory Center of Expertise  
North America

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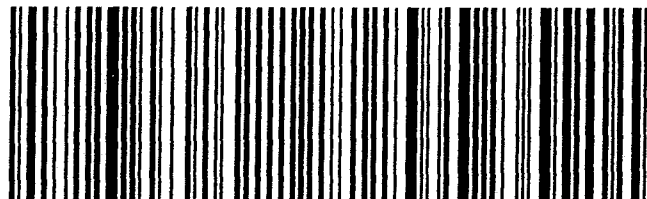
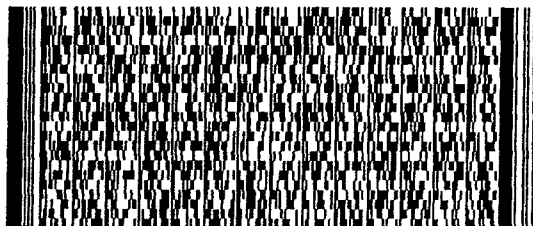
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